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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,950	02/19/2004	Andrew C. Hiatt	EPI3009 (068904-0507)	4806
30542	7590	09/06/2006	EXAMINER	
FOLEY & LARDNER LLP			WESSENDORF, TERESA D	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	
			1639	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/783,950

Applicant(s)

HIATT ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-34, 38-63 and 67-71 is/are pending in the application.
- 4a) Of the above claim(s) 25-34, 38-52, 56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-55, 58-63 and 67-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/1/2006 has been entered.

***Status of Claims***

Claims 25-34, 38-63 and 67-71 are pending

Claims 25-34, 38-52 and 56-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 53-55, 58-63 and 67-71 are under examination.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 53-55, 58-63 and 67-71, as amended, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim array in eukaryotic cells comprising of the properties as recited in (a)-(d) would read on a naturally occurring CHBP present in all eukaryotic cells. [The preamble of transfecting relates more to a method step rather than to a positive identification of the composition, CHBP. The preamble, if any is accorded, little weight, especially since it does not affect or correlate to the body of the claims.] See e.g., claims 59-61.

#### ***Withdrawn Rejections***

In view of the 37 CFR 1.32 declaration of Dr. Hiatt and applicants' arguments, the 35 USC 112, first paragraph rejection in the last Office action has been overcome.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-55, 58-63 and 67-71, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with

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the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a written description of a heavy chain binding protein (CHBP) array in a eukaryotic cell wherein the CHBP polypeptide is recited to have the recited properties of (a)-(d). There seems to be no correlation between the specific IgBP array transfected in plant cells as described in the detail description i.e., Examples with the general statements reciting the properties of the polypeptide. None of the detail description describes a CHBP array in a eukaryotic cell having the stated properties of the IgBP. It does not describe an array with polynucleotides encoding a protein that is at least 75 % identity to a 25 consecutive amino acid portion of Ig light chain variable region and etc. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. The specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the array with the critical features of the encoded polypeptide. Page 10, lines 8-24 recited by

applicants refer to the IgBP not in array form. Thus, no identifying characteristics or properties of the array with IgBP defined as a percent of the whole is described in the specification. No guidance or direction has been provided in the specification such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Furthermore, the disclosure does not describe an array comprising at least 1,000 and 10,000 different binding proteins assembled by the cells in an array.

#### ***New Matter Rejection***

The claimed description of a CHBP array that result from transecting "***a population of eukaryotic cells with a library of at least two different CHBP*** ....said library of at least two different CHBP polynucleotide wherein each CHBP polynucleotide encodes...." is not supported in the as-filed specification. MPEP 714.02 specifically recites that applicants point out where in the as-filed specification the limitations can be found.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-55, 58, 63 and 67-71, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 53 is an omnibus claim in that it fails to point out what is included or excluded by the claim language. For example, it is not clear whether an array of eukaryotic cells containing the CHBP arrays or simply the CHBP arrays are intended. The combination of method steps e.g., transfecting with the compound claims renders the claim confusing. There seems to be no nexus between the preamble and the body of the claim.

2. Claims 54-55 and 58-63 and 67-71 are unclear in the use of the language "**a binding protein array**". The base claim recites a CHBP array. The use of inconsistent terminologies provide for confusion and ambiguity.

3. Claims 59-62 are unclear as to how the binding proteins are assembled by the cells in the array. These claims appear to be inconsistent with the base claim CHBP array in the cells.

**Claim Rejections - 35 USC § 103**

Claims 53-55, 58-63 and 67-71, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over by Ma et al

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(Eur. J. Immunol.) or Hiatt (Nature) in view of Dellaporta (USP 6569648). [This rejection is based on the interpretation that the claimed at least 75% identical to a constant region tailpiece of a mu or alpha chain of native Ig heavy chain (i.e., the full length sequence of CHBP or Ig.) as reiterated below.

Ma discloses at page 132 under Materials and methods section including Fig. 1, the different forms of heavy chain (array as claimed) transformed in plants i.e., Plant G13, Plant G1/A and G2/A. Ma at page 133 under the RESULTS section, paragraph 3.2 discloses that 22 transgenic plants were regenerated from the transformation with light or heavy chain constructs. The antigen binding capability of the mab is disclosed at page 138, paragraph 3.4 including the figures up to page 137. At page 138, paragraph 3.5, Ma discloses the different eukaryotic cells i.e., mouse and plant. Hiatt at pages 469-70 basically discloses a similar transgenic plant with antibodies. However, each of these references does not disclose an array of CHBP in eukaryotic cells. However, Dellaporta teaches at e.g., col. 3, line 50 up to col. 4, line 10 that the labeled gene-specific probes may then be hybridized and detected directly on the arrays, allowing simultaneous screening of a large number of pools and ultimate identification of one or more insertional mutants. Accordingly, it would have been obvious to one having



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ordinary skill in the art at the time the invention was made to make the CHBP of either Ma or Hiatt into array for the advantage of simultaneous screening of a large number of pools and ultimate identification of one or more insert ional mutants as taught by Dellaporta. The claimed features of the heavy chain i.e., its binding capability (kD value) and covalent (disulfide) bond formation are properties considered inherent to the full-length heavy chain. [Note these properties are normally possess by the native mab (Ig).] Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

In view of the new prior art above, the arguments against Ma is moot.

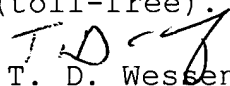
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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
September 4, 2006